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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,971

09/30/2003

Gary K. Michelson

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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

12/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/674,971	<b>Applicant(s)</b> MICHELSON, GARY K.	
	<b>Examiner</b> David H. Willse	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on September 24, 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-24-09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 33, 34, 36, 37, 41, 50, 51, 54, and 56 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steffee, EP 0 392 076 A1, which discloses an artificial implant **5** having upper and lower surfaces at least partially arcuate in a transverse plane by virtue of the spherical particles **26** (column 7, lines 35-38; Figure 2) and the rounded edges (innately defined by minute or infinitesimal radii) of the conical projections **28**. The non-linear leading and trailing ends conform to and overlies the apophyseal rims of adjacent vertebral bodies (Figure 1; column 5, lines 30-32). Regarding claims 33 and 34, reference is made to column 7, lines 44-47. Regarding claims 36 and 37, linear and rotational movements would have been inherent in order to insert and align the implant **5** into the designated opening formed between vertebrae **6** and **7** (Figure 1).

Claims 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee, EP 0 392 076 A1. Regarding claim 30, a driver instrument would have been immediately obvious in order to facilitate grasping or engaging of implant **5** during deployment. Regarding

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claim 35, drilling would have been obvious in order to form the seats or depressions (column 8, lines 1-3), for example.

Claims 29, 30, 33, 34, 36, 37, 41, 50, 51, 54, and 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schug et al., EP 0 599 419 A2, which teaches arcuate upper and lower surfaces (column 3, lines 12-13; column 4, lines 1-6; column 5, lines 36-40) and a periphery that conforms to and overlies the apophyseal rim (column 1, lines 37-39; column 3, lines 19-26; etc.). Regarding claim 30, particular attention is directed to column 3, lines 38-42.

Claims 31, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schug et al., EP 0 599 419 A2. Regarding claims 31 and 32, pre-loading with bone or BMP the hollows partially occupied by the open-pore or open-celled metal structure 6 (column 3, lines 5-9; Figures 1-3) would have been obvious in order to enhance osseointegration (column 1, lines 44-53; column 2, lines 36-39; etc.). Regarding claim 35, drilling the opening would have been obvious in order to remove soft tissue near the vertebral concave curvature (column 4, lines 4-6), for example.

Claims 39, 40, 42-48, 52, 53, 55, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Steffee or Schug et al. and Brantigan, US 5,192,327. Steffee and Schug et al. lack a *pair* of implants for the spinal disc replacement. However, such a variant was well known in the art at the time of the present invention, as seen from Figure 2 of Brantigan. To re-design the single artificial disc of Steffee or Schug et al. so as to take on the form of a pair of juxtaposed implants would have been an obvious modification in order to enable deployment in the posterior lumbar area (Brantigan: column 2, lines 7-11), to provide the option of “partial corpectomy operations” (Brantigan: column 4, lines 57-58), and/or to reduce

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incision opening sizes, with further motivation have been provided by the similarity in form and purpose of the Brantigan device (e.g., Figures 1, 2, 6, and 11) to that of Steffee or Schug et al. Moreover, such a modification would have led to nothing more than predictable results, because the side-by-side configuration would similarly provide for immediate and long-term stabilization. Conversely, modifying the Brantigan embodiment of Figure 2 by forming complementary convex and concave surfaces as discussed above for Steffee or Schug et al. would have been obvious in order to improve the initial securement of the implant.

Claims 38 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schug et al., Brantigan, and Crozet, WO 98/48738 A1, via related US 6,855,168 B2. A screw or screws spanning the disc space and threadingly engaging the adjacent vertebrae, as taught in Crozet (Figures 1, 28, 42; column 1, lines 43-47; column 2, lines 59-61; column 8, lines 12-19; etc.), would have been an obvious supplement or substitute for the engagement features of Schug et al. and Brantigan in order to improve anchorage and to promote bone fusion via screw cutting edges (column 4, lines 21-24; etc.), with further motivation having been provided by the similarities in design and function of the three teachings. Attention is also directed to the Office action of July 7, 2009, in parent application serial no. 09/792,679.

The Applicant's remarks have been considered but are deemed to be moot in view of the new grounds of rejection presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-

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4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/  
Primary Examiner  
Art Unit 3738**